

FDA approves durvalumab with chemotherapy for mismatch repair deficient primary advanced or recurrent endometrial cancer

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On June 14, 2024, the Food and Drug Administration approved durvalumab (Imfinzi, AstraZeneca UK Limited) with carboplatin plus paclitaxel followed by single-agent durvalumab for adult patients with primary advanced or recurrent endometrial cancer that is mismatch repair deficient (dMMR).

Full prescribing information for Imfinzi will be posted on [Drugs@FDA](#).

Efficacy and Safety

Efficacy was evaluated in DUO-E (NCT04269200), a randomized, multicenter, double-blind, placebo-controlled trial in patients with primary advanced or recurrent endometrial cancer. Tumor MMR status was a stratification factor and was assessed using an immunohistochemistry tumor tissue test. Patients were randomized (1:1:1) to one of the following treatment arms:

- Durvalumab 1,120 mg with carboplatin plus paclitaxel every 3 weeks for a maximum of 6. Following completion of chemotherapy, patients received durvalumab 1,500 mg every 4 weeks as maintenance until disease progression.
- Placebo with carboplatin and paclitaxel every 3 weeks for a maximum of 6 cycles. Following completion of chemotherapy, patients received placebo every 4 weeks until disease progression.
- An additional investigational combination regimen.

The major efficacy outcome measure was progression-free survival (PFS), determined by investigator assessment using RECIST v1.1.

While a statistically significant improvement in PFS was observed in the overall population for durvalumab with carboplatin plus paclitaxel compared to carboplatin and paclitaxel alone, the improvement in the overall population was primarily attributed to patients with dMMR tumors based on an exploratory analysis by tumor MMR status.

In 95 patients with dMMR tumors, median PFS was not reached (NR) (95% CI: NR, NR) in the durvalumab arm and was 7 months (95% CI: 6.7, 14.8) in the placebo arm (hazard ratio: 0.42 [95% CI: 0.22, 0.80]). Overall survival, an additional efficacy outcome measure, was immature at the PFS analysis.

The most common adverse reactions (>25%) with durvalumab in combination with carboplatin and paclitaxel were peripheral neuropathy, musculoskeletal pain, nausea, alopecia, fatigue, abdominal pain, constipation, rash, diarrhea, vomiting, and cough. The prescribing information provides the complete adverse reactions.

The recommended durvalumab dose for patients with a body weight ≥ 30 kg is 1,120 mg with carboplatin plus paclitaxel every 3 weeks for 6 cycles, followed by single-agent durvalumab 1,500 mg every 4 weeks. The recommended durvalumab dose for patients with a body weight of < 30 kg is 15 mg/kg with carboplatin and paclitaxel every 3 weeks for 6 cycles, followed by durvalumab 20 mg/kg every 4 weeks.

Content current as of:
06/14/2024

MERCK EX1272

Merck Sharp & Dohme LLC v. The Johns Hopkins University

IPR2024-00625

Expedited Programs

This review used the [Assessment Aid](#), a voluntary submission from the applicant to facilitate the FDA's assessment.

Healthcare professionals should report all serious adverse events suspected to be associated with the use of any medicine and device to FDA's [MedWatch Reporting System](#) or by calling 1-800-FDA-1088.

For assistance with single-patient INDs for investigational oncology products, healthcare professionals may contact OCE's [Project Facilitate](#) at 240-402-0004 or email OncProjectFacilitate@fda.hhs.gov.

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